

**Requirement for Restriction
~and~
Election of Species**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 (all in part) drawn to 2,7a-dihydro-1*H*-pyrrolo[1,2-*c*][1,3]oxazol-3-ones, and a pharmaceutical composition comprised thereof, classified in class/subclass 548/217; class/subclass 514/375 for the composition (wherein X=-CH₂-; Y=-O-; Z=-C(O)-).
- II. Claims 1-7 (all in part), drawn to 1,2,5,7a-tetrahydro-3*H*-pyrrolo[1,2-*c*]imidazol-3-ones, classified in class/subclass 548/300.4; class/subclass 548/387 for the composition (wherein X=-CH₂-; Y=-NH-; Z=-C(O)-).
- III. Claims 1, 2, 6 and 7 (all in part), drawn to 1,2,6,8a-tetrahydro-pyrrolo-[1,2-*a*]pyrazin-3(4*H*)-ones, classified in class/subclass 544/349; 514/249 for the composition (wherein X=-CH₂-; Y=-NH-C(O)-; Z=-CH₂-).
- IV. Claims 1-5 and 7 (all in part), drawn to other types of heterocyclic compounds, and a composition comprised thereof, classified in various classes and subclasses; class 514, various classes and subclasses for the composition.
- V. Claims 8-10, 21, 22, 32 and 33 drawn to methods wherein the compounds as set forth in Group I, II, III or IV are administered, classified in class 514, various subclasses (as indicated above in Groups I, II, III and IV for the compositions).

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and

Art Unit: 1624

there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include

(i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

Art Unit: 1624

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the instant case, the different values for X, Y and Z provide for patentably distinct heterocyclic core motifs. A reference which anticipates or renders obvious one of the heterocyclic cores likely will not render any of the others anticipated or obvious. In the instant case also, the methods as set forth in Group V are likely to raise different non-prior art issues under 35 U.S.C. 112, first paragraph and/or 35 U.S.C. 101.

If Group V is elected in response to this Requirement, further Restriction will be required.

This Requirement is Further Set Forth as Follows:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be

Art Unit: 1624

applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

This Requirement is Subject to the Following Conditions:

The examiner has required restriction between compounds and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method of use claims that depend from or otherwise include all the limitations of the patentable compound will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims and method of use claims may be maintained. Withdrawn method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 9:00am to 5:00pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Zachary C. Tucker/
Primary Examiner, Art Unit 1624